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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/226,597	01/07/1999	JULIO PIMENTEL	585-017-84	9844

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EXAMINER	
GABEL, GAILENE	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 10/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/226,597	PIMENTEL, JULIO	
	Examiner	Art Unit	
	Gailene R. Gabel	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *6/2/03 , 11/7/03, and 8/23/04*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 9-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 9-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/2/03 has been entered.

Amendment Entry

2. Applicant's amendment and response filed 8/23/04 is acknowledged and has been entered. Claim 1 has been amended. Applicant's amendment and response filed 11/7/03 is also acknowledged and has been entered. Claims 2 and 6 have been amended. Claims 7 and 8 have been cancelled. Claims 10 and 11 have been added. Accordingly, claims 1-6 and 9-11 are pending and are under examination.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-6 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, preamble, is vague and indefinite in reciting, "regulating" because the term "regulating" is a subjective term that lacks a comparative basis for defining its metes and bounds.

Claim 1 is vague and indefinite in reciting, "an effective amount of liposome-encapsulated immunoglobulin" because the term "effective" as used lacks a comparative basis for defining its metes and bounds.

Claim 1 appears redundant in reciting, "an effective amount of a liposome-encapsulated immunoglobulin against lipase effective to inhibit body-weight gain". Perhaps, Applicant intends, "an amount of a liposome-encapsulated immunoglobulin against lipase effective to inhibit body-weight gain."

In claim 3, "if" should be --is--.

Claim 6 is vague and indefinite in reciting, "an effective amount of liposome-encapsulated immunoglobulin" because the term "effective" as used lacks a comparative basis for defining its metes and bounds.

Claim 6 appears redundant in reciting, "an effective amount of a liposome-encapsulated immunoglobulin against lipase and effective to inhibit body-weight gain". Perhaps, Applicant intends, "an amount of a liposome-encapsulated immunoglobulin against lipase effective to inhibit body-weight gain."

Claim 9 appears to have a typographic error in reciting, "25 – 100 mg/kg". As previously presented, it should recite, "25 – 1000 mg/kg".

New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-6 and 9-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

In this case, the specification does not appear to provide literal support for the recitation of "an amount of liposome-encapsulated immunoglobulin against lipase effective to inhibit body-weight gain". In page 2, lines 7-9 of the specification, Applicant discloses that the amount of body weight gained by an animal as a result of eating is **decreased** by including encapsulated antilipase antibodies. Further in page 3, lines 24-26, the specification provides that "the present invention provides decreased body weight gain per unit of food". Data in Example 5 also appears to show substantial decrease of body weight gained by antilipase antibody treated rats. Lastly, page 6 of the specification provides that the body weight gained by antilipase antibody treated rats is "much less" than the control group. None of the originally filed claims appear to recite

the limitation in question. Recitation in the claims lacking literal support in the specification or originally filed claims constitutes new matter.

Scope of Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-6 and 9-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for regulating body weight of rats by feeding them a fat-containing diet and an amount of liposome-encapsulated immunoglobulin against lipase effective to reduce body weight gain, does not reasonably provide enablement for a method wherein the liposome-encapsulated immunoglobulin against lipase is effective to inhibit body-weight gain in any and all animals, as recited in claim 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement requires that the specification teach those skilled in the art to make and use the invention without undue experimentation. Factors to be considered in determining, whether a disclosure would require undue experimentation include 1) the nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of

working examples, 6) the quantity of experimentation necessary, 7) the relative skill of those in the art, and 8) the breadth of the claims.

The nature of the invention- the invention is directed to a method for regulating the body weight of an animal, by feeding the animal a fat-containing diet and an amount of a liposome-encapsulated immunoglobulin against lipase effective to reduce body weight gained.

The state of the prior art- the prior art of record fails to disclose a method that is applicable to any and all animals wherein an effective amount of liposome encapsulated immunoglobulin specific for lipase added to a fat-containing diet is capable of inhibiting body weight gain of any animal.

The predictability or lack thereof in the art- there is no predictability based on the instant specification that the claimed method will work in reducing body weight gain in other animals other than rats, as shown in the examples where the rats are fed a high fat diet. There is no predictability based on the instant specification that the liposome encapsulated immunoglobulin against lipase added to fat-containing diet will work in totally inhibiting body weight gain of any and all animals using the claimed method.

The amount of direction or guidance present- appropriate guidance is provided by the specification for the claimed method to effectively reduce body weight gain in rats that are fed a high fat diet. However, the specification fails to provide guidance to enable the claimed method to inhibit body weight gained by all animals that are fed a fat-containing diet and the liposome-encapsulated immunoglobulin against lipase.

The presence or absence of working examples- working examples are provided in the specification that show a reduction in weight gain in rats after being fed a high fat diet using the claimed method. There are no working examples that show analogous results in other animals that are fed a high fat diet and the liposome-encapsulated immunoglobulin against lipase presumably effective in inhibiting body weight gain, which is encompassed by the broad scope of the instant claims.

The quantity of experimentation necessary- it would require undue amount of experimentation for the skilled artisan to make and use the method as claimed, considering the scope of animal types encompassed by the claim.

The relative skill of those in the art-the level of skill in the art is high.

The breadth of the claims- as recited, the instant claims are directed to a method that is applicable to inhibiting body weight gain of any and all animals by feeding them a fat-containing diet and an amount of liposome-encapsulated immunoglobulin against lipase effective to inhibit body weight gain.

While the specification exemplifies a reduction in weight gain in rats that have been fed a high fat diet using the claimed method, the specification does not show working examples of the claimed method capable of inhibiting body weight gain in rats and any other animal. The fact that the claimed method appears to work in reducing body weight gain in rats is not sufficient to enable the breadth of the claimed method for specifically inhibiting body weight gain in rats and any or all animals. Additionally, the specification does not establish a direct correlation between rats and all animals which would lead the skilled artisan to say that if the claimed method works in reducing body

weight gain in rats then it should work in reducing body weight gain for all animals to enable the breadth of the claimed method. As a specific example, the specification lacks any correlation between rats and humans. The specification does not provide a teaching that suggests that rats can be considered an acceptable animal model for weight reduction in humans. Page 3 of the specification makes reference to controlling weight in mammals, avians, and any animal having a pancreas or that secretes lipase but provides no showing that the claimed method works for specifically inhibiting body weight gain in rats or any other animal. While it is not necessary to show working examples for every possible embodiment, there should be sufficient teachings in the specification that would suggest to the skilled artisan that the breadth of the claimed method is enabled. This is not the case in the instant specification. Thus, the claimed method is only enabled for reducing body weight gain in rats.

In view of the teachings of In re Wands, 8 USPQ2d 1400, it has been determined that the level of experimentation required to enable the breadth of the claims is undue. It has been set forth above that 1) the experimentation required to enable the claimed method for any and all animals that are fed a fat-containing diet and a liposome-encapsulated immunoglobulin against lipase effective to inhibit body weight gain, would be great as 2) there is no experimental evidence provided that would indicate that the claimed method would work in reducing body weight gain in animals, other than rats; 3) there is no proper guidance that shows that rats are acceptable animal models for any and all animals in the instant specification, 4) the nature of the invention is a method that would reduce body weight gain of animals by feeding them a fat-containing diet and

liposome-encapsulated immunoglobulin against lipase effective to reduce body weight gain, 5) the relative skill of those in the art is high, yet 6) the state of the prior art has been shown to be unpredictable as evidenced by the fact that no prior art has been cited that shows inhibition in body weight gain in animals after feeding them a fat-containing diet and an amount of liposome-encapsulated immunoglobulin against lipase effective to inhibit body weight, and lastly 7) the claims broadly recite a method for regulating the body weight gain of animals by feeding them a fat-containing diet and an amount of liposome-encapsulated immunoglobulin against lipase effective to inhibit body weight gain, without specifically stating how this can be done without undue experimentation.

Therefore, it is maintained that one of ordinary skill in the art could not make and use the invention as claimed without undue experimentation.

Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-6 and 9-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The specification does not provide a teaching of an interaction, i.e. binding or reaction, that takes place between immunoglobulins against lipase and lipase antigen in the gastrointestinal tract to enable regulation of body weight in any and all animals by feeding them a fat-containing diet and a liposome encapsulated immunoglobulin against lipase effective to inhibit body-weight gain. A general comment at page 1, lines 9-10 in the specification states that lipases hydrolyze a portion of dietary lipid, i.e. triacyglycerol, to fatty acids and glycerol in the gastrointestinal tract. However, there is no description of how the immunoglobulins against lipase, if released in the GI tract, are absorbed or caused to migrate across intestinal wall to bind or react with plasma lipase antigen to systemically inhibit weight gain, as encompassed by the claimed invention. The specification provides no teaching of how immunoglobulin binding to lipase, if present, causes the active site of the antigen to be inhibited since immunological binding of antilipase antibodies to lipase does not equate to blocking the catalytic epitope of lipase antigen. Therefore, the capability to generate anti-lipase antibodies from lipase of unknown origin that can act upon lipase antigen in any and all animals, to react or bind in such a way that its catalytic epitope is blocked, either in the GI tract or systemically in the plasma and inhibit weight gain, is an unpredictable task.

The structure of lipase antigen from which immunoglobulins against lipase are generated from, so as to enable interspecies cross-reactivity between animals, i.e. mammalian and avian, and regulate body weight gained by feeding them an amount of the liposome encapsulated immunoglobulin against lipase that is effective to totally inhibit body weight gain as required by claim 1, is not characterized and described in the

specification. General comments on the development and generation of antilipase polyclonal antibodies from avian eggs are insufficient to establish the nature or potency of the antibodies to provide interspecies cross-reactivity with lipase of any or all animals for purposes of regulating body weight by inhibiting body weight gained. Antibodies generated from undefined mammalian lipase sources, i.e. bovine, may not necessarily have specificity for and cross-reactivity with any other lipase of mammalian species, i.e. human or avian species, so as to inhibit body weight gained. The instant specification fails to establish a correlation between lipase of humans and lipase of avian or the rat species, for example. Generation of antibodies that react or bind with lipase of any and all species, specifically at its catalytic site, so as to inhibit body weight gain in any and all animals, would appear to be an unpredictable task. Further, physiological function and metabolism between individuals and between species may account for enhanced or reduced functional potency of the immunoglobulins against lipase in reacting with a given lipase structure. Thus, one skilled in the art would reasonably conclude that even if one has knowledge in generating antilipase antibodies from different species such as set forth in Applicant's disclosure, some level of function of the anti-lipase antibodies in inhibiting weight gain can be affected by the structure of each individual lipase antigen that is endogenous to any given species.

Response to Arguments

7. Applicant's arguments with respect to claims 1-6 and 9-11 have been considered but are moot in view of the new grounds of rejection.

Prior Art

8. Currently, claims 1-6 and 9-11 are clear of the prior art of record.

9. No claims are allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (571) 272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gailene R. Gabel
Patent Examiner
Art Unit 1641
October 21, 2004

Christopher L. Chin

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10/24/04